FEDERAL TRADE COMMISSION
WASHINGTON, D. C. 20580

OFFICE OF THE SECRETARY

15 DEC 1981

Ernest Pepples
Senior Vice President
and General Counsel
Brown and Williamson Tobacco Corporation
1600 West Hill Street
P.O. Box 35090
Louisville, Kentucky 40232

Dear Mr. Pepples:

The Commission wishes to apprise you of the status of the investigation concerning the request by the R.J. Reynolds Tobacco Company that the cigarette holder currently used in the Commission's Cigarette Laboratory testing procedure be modified. On October 26, 1981, the Commission notified you that no action would be taken until Brown and Williamson's response to the other companies' submissions was reviewed. The Commission instructed the staff to review the material and to prepare a supplemental memorandum reporting the results of that review no later than November 20. Staff has completed and the Commission has reviewed this supplemental memorandum.

The Commission has determined that the substantial evidence obtained to date raises serious questions regarding whether the current testing methodology assesses Barclay's "tar" delivery accurately. Therefore, the Commission has ordered that the attached statement (Attachment I) be included in the new Cigarette Laboratory Report of "Tar," Nicotine and Carbon Monoxide Content of the Smoke of 200 Varieties of Cigarettes. The statement acknowledges the pendency of, and describes the issues raised by, this investigation. The Commission has also ordered that this statement be referenced by a footnote next to the test results for Barclay cigarettes.

Based upon the staff's review of the evidence submitted to date, the Commission has further determined that this investigation is not complete and that a number of scientific questions remain. These questions fall into two general categories. First, a number of methodological concerns have been raised about those studies that appear to be the most probative for resolving this matter. Second, additional information about these same studies appears necessary to evaluate their results. To expedite the resolution of this

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investigation and to give you an opportunity to address these questions and concerns, the staff has prepared the attached list (Attachment II), which describes the methodological concerns that have been raised and the additional information the staff believes is necessary to conclude this investigation.

The Commission appreciates your cooperation to date in this matter and recognizes that you and the other members of the cigarette industry voluntarily have already submitted a substantial amount of scientific evidence. To resolve this important matter as expeditiously as possible, the Commission requests that, if you elect to file any additional comments, data or research in response to Attachment II to this letter, those comments and any supporting data be filed no later than February 15, 1981. Upon receipt of this information, the Commission's consultants on this matter will review this material and submit their final reports to the staff within 30 days. The Commission will provide you with 15 days to review and comment upon the consultants' reports. Based on all of the evidence available, the Commission will then determine what action, if any, to take in this matter.

By direction of the Commission.

Carol M. Thomas
Secretary

Attachments

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ATTACHMENT I

Statement recommended for inclusion in text of Report of "Tar," Nicotine, and Carbon Monoxide of Smoke of 200 Varieties of Cigarettes

A group of cigarette companies has filed a complaint with the Commission alleging that the current cigarette testing methodology does not accurately assess the "tar" and nicotine that Barclay cigarettes deliver relative to the "tar" and nicotine that other cigarette brands deliver. The complainant cigarette companies further allege that Barclay, a 1 mg. cigarette under the current FTC test method, delivers more "tar" to the smoker than do other 1 mg. "tar" cigarette brands.

The complainant cigarette companies state that a cigarette manufacturer can reduce the "tar" delivery of a cigarette by a variety of different methods. One way to decrease "tar" delivery involves diluting the cigarette smoke inhaled with air brought into the filter through some form of ventilation. The higher the percentage of diluted air inhaled, the lower the "tar" delivery. Methods to increase the amount of air dilution vary among cigarette brands. Many low "tar" cigarettes have a filter surrounded by porous paper with one or more rows of ventilating holes encircling the filter. When the filter is puffed, air enters the filter through the ventilation holes and mixes with the smoke.

In the Barclay filter, air entering the ventilation holes travels into the smoker's mouth through four grooves surrounding the filter. The complainant cigarette companies allege that when consumers smoke Barclay cigarettes, the four grooves either collapse or are in some way blocked. When tested in the FTC laboratory using the current cigarette holder, however, the companies allege that the grooves do not collapse and are not blocked. Thus, it is contended, the Commission's current testing methodology does not accurately measure the relative level of "tar" that Barclay delivers to smokers when compared with other 1 mg. "tar" cigarettes. The Commission is currently investigating these allegations, and has not made a final determination on the merits. An asterisk is appended to the test scores included in this report that this investigation may affect.

Reference accompanying the asterisk next to Barclay's test scores in the tables of the Report "Tar," Nicotine and Carbon Monoxide Content of 200 Varieties of Cigarettes

* See statement in accompanying text concerning Barclay cigarettes.

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ATTACHMENT II

A wide variety of scientific studies have been submitted in this matter. The staff and the Commission's consultants have carefully reviewed each study, and the Commission will consider each study in resolving this controversy. Although questions and concerns have been raised about each study submitted, the staff believes that by providing each cigarette company a specific opportunity to address the questions and methodological concerns raised about the air dilution research submitted by Philip Morris, Inc. and the cotinine research submitted by the Brown and Williamson Tobacco Corporation, this investigation can be most expeditiously concluded.

The following questions and concerns have been raised about the methodology used in the Philip Morris air dilution research.

1.) Questions have been raised about the impact of the sample size on the validity and reliability of the results.

2.) Questions have been raised regarding whether the use of Philip Morris employees as subjects biases the results.

3.) Questions have been raised regarding whether the fact that some of the subjects may have known the purpose of the study biases the results.

4.) Questions have been raised regarding whether the use of Philip Morris employees to conduct this research biases the results.

5.) Questions have been raised regarding whether the special apparatus designed by Philip Morris for this research to measure air dilution prevents normal smoking behavior, and regarding whether the placement of the dental dam on the cigarette filter biases the results against Barclay.

6.) To what extent did the data for each subject tested vary? Does the raw data for each subject still exist? Can it be made available to the Commission staff?

7.) What cigarette did each subject tested customarily smoke? If they smoked a cigarette during the air dilution test different from their customary cigarette, what impact, if any, did this fact have on the results? Was each subject tested also tested on their customary cigarette? If not, why not?

The following questions and concerns have been raised about the cotinine research conducted by Dr. Gio Gori and submitted by Brown and Williamson.

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1.) Barclay was the only cigarette tested that yields more than 0.1 mg. nicotine per cigarette by the F.T.C. method. Questions have been raised about the usefulness of this data absent results from other cigarettes with a yield of 0.2 mg. nicotine per cigarette by the F.T.C. method. In addition, it has been suggested that this data be supplemented by tests on a series of cigarettes with yields over 0.2 mg. nicotine per cigarette by the F.T.C. method, in order to evaluate more accurately whether a dose-response relationship exists between the F.T.C. method and the plasma cotinine research. Does this data exist? Can it be made available to the Commission staff? To what extent would this data be useful in evaluating the merits of cotinine research?

2.) The data for the twelve subjects from Study A was extracted from a separate ongoing study. Did that study yield any cotinine data on subjects who smoked cigarettes other than Carlton, Barclay, or Cambridge? If so, what was that data?

3.) Does any cotinine data exist on subjects who smoked cigarettes other than those cigarettes tested in Studies A and B. If so, what is that data?

4.) What scientific literature exists to indicate that cotinine research using the methods and equipment used by Dr. Gori is sensitive and reliable enough to distinguish accurately between, or measure at all, the nicotine yields at issue in this matter.

5.) It has been suggested that one method of validating the existence of a relationship between the F.T.C. testing program and cotinine research is to conduct the cotinine research over a period of time on a large enough sample of smokers, each smoking the cigarette they regularly smoke, to determine whether there are any differences in the cotinine levels between each group of smokers. Although this approach has drawbacks in terms of variations in individual behavior and metabolism, it has the advantage of avoiding potential error in the results due to any smoker compensation from brand switching. Does this type of data exist? If so, what is the data? To what extent would this data be useful in evaluating the merits of cotinine research?

6.) Among those subjects included in Studies A and B, what cigarette brand did each customarily smoke?

7.) To what extent did the data for each subject tested vary? Does the raw data for each subject still exist? Can it be made available to the Commission staff?

8.) On page 13 of Dr. Gori's report, he notes that cotinine recovery averaged 81% in ten samples. To what extent did

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each sample vary? Does the data from this "recovery study" exist? If so, can it be made available to the Commission staff along with a more detailed description of the methodology used in doing the "recovery study?"

9.) What was the analytical calibration curve of the gas chromatograph calibration?

10.) Was data recorded on the height, weight, sex, and age of each subject tested? Can this data be made available to the Commission staff?

The purpose of listing these particular questions and concerns is to help focus the remainder of this investigation. You should feel free however, to comment on or provide additional information about any of the other studies already submitted, or to provide results of additional research, if you so desire.

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Identical letters (not attached) were sent to:

2. Abe Krash, Counsel for PM
3. Joseph Greer, Liggett
4. Samuel Witt, RJR
5. Arthur Stevens, Lorillard
6. Arnold Hensen, American Brands
7. Alexandra Holtzman, PM
8. Ernest Pepples, B&W

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